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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|------------------------------------|----------------------|------------------------------|------------------|
| 10/849,374 | 05/19/2004 | Bjorn Olstad | 15-DS-00549 (MHM 13109US0 | 6522 |
| | 7590 05/01/200 S HELD & MALLOY, | EXAMINER | | |
| 500 WEST MADISON STREET | | | CHAO, ELMER M | |
| SUITE 3400 CHICAGO, IL 60661 | | | ART UNIT | PAPER NUMBER |
| , | | | 3737 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/01/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|--|
| Office Action Summary | | 10/849,374 | OLSTAD, BJORN | | | | |
| | | Examiner | Art Unit | | | | |
| | | ELMER CHAO | 3737 | | | | |
| Period fo | The MAILING DATE of this communication a or Reply | opears on the cover sheet with th | ne correspondence address | | | | |
| WHIC - Exter after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REP CHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory perior to reply within the set or extended period for reply will, by staticated by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICAT 1.136(a). In no event, however, may a reply but the distribution of the application to become ABANDO | ION. be timely filed from the mailing date of this communication. DNED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1) | Responsive to communication(s) filed on 19 | December 2007 | | | | | |
| • | Responsive to communication(s) filed on <u>19 December 2007</u> . This action is FINAL . 2b) This action is non-final. | | | | | | |
| 3) | , _ | | | | | | |
| ٥,١ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4)⊠ | ☑ Claim(s) <u>1-21</u> is/are pending in the application. | | | | | | |
| , | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| | ☐ Claim(s) is/are allowed. | | | | | | |
| | ☐ Claim(s) <u>1-21</u> is/are rejected. | | | | | | |
| · · | Claim(s) is/are objected to. | | | | | | |
| - | Claim(s) are subject to restriction and | or election requirement. | | | | | |
| Applicati | on Papers | | | | | | |
| 9)□ | The specification is objected to by the Exami | ner. | | | | | |
| • | The drawing(s) filed on is/are: a) ☐ a | | ne Examiner. | | | | |
| , | Applicant may not request that any objection to the | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 2) Notice 3) Inform | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 4) Interview Summ Paper No(s)/Ma 5) Notice of Inform 6) Other: | | | | | |

Art Unit: 3737

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 12/19/2007.

Response to Arguments

2. Applicant's arguments filed 12/19/2007 have been fully considered but they are not persuasive.

Regarding Applicant's arguments with respect to newly amended claims 1 and 13, Examiner asserts that all of the limitations are still read on by Roundhill et al. Roundhill et al. teach presetting values in an analytical instrument using said clinically relevant information (col. 10, lines 13-15). Specifically, the clinically relevant information would be in this case the "control points beneath the border". These points are then Doppler processed so inherently an analytical instrument would have to be preset with those values so that the information can be processed by the analytical instrument running the Doppler process.

Regarding claims 8-10, a new ground of rejection has been provided as necessitated by the amendments.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.

Application/Control Number: 10/849,374

Art Unit: 3737

Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claims 1, 3, 4, 5, and 7** are provisionally rejected on the ground of nonstatutory double patenting over claims 6, 9, and 11-16 of copending Application No. 11/082,540. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a method of using an ultrasound machine including locating at least one anatomical landmark; locating at least one clinically relevant location based on the at least one anatomical landmark; extracting clinically relevant information from said at least one clinically relevant location within the heart; and displaying indicia overlaying said at least one clinically relevant location.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant

Application/Control Number: 10/849,374

Art Unit: 3737

application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. Claims 1-5, 7, 10, and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/848,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are narrower in scope than the present application claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35
U.S.C. 102 that form the basis for the rejections under this section made in this
Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Roundhill et al. (U.S. 6,447,453 B1; also see Publication U.S. 2002/0072672 A1).

Regarding **claims 1-4**, **and 7**, Roundhill et al. teach a method for using an ultrasound machine comprising locating at least one anatomical landmark within the cardiac structure and generating position information of said at least one

anatomical landmark comprising the apex of the heart (Fig. 4); locating at least one clinically relevant location within the heart based on said position information of said at least one anatomical landmark (Fig. 8, see the border of the LV); and extracting clinically relevant information from said at least one clinically relevant location within the heart, wherein the clinically relevant information can comprise Doppler profile information (col. 10, lines 12-15), wherein the extracting involves presetting at least one m-mode, Doppler sample volume, and region-of-interest (col. 9, line 62 – col. 10, line 51); and displaying indicia overlaying said at least one clinically relevant location on a display of said ultrasound machine (Fig. 5, ltems 26, 36, & 46; Fig. 11, Item 100).

Regarding **claims 8-10**, Roundhill et al. teach the preset values being m-mode, Doppler sample volume, or a ROI (col. 9, line 62 – col. 10, line 10, "m-mode"; col. 10, lines 10-20).

Regarding **claim 5**, Roundhill et al. teach the clinically relevant location being the LV portion of the heart (see Fig. 13a).

Regarding **claim 6**, Roundhill et al. teach that locating at least one clinically relevant location includes performing edge detection of said at least one myocardial segment of the heart to locate endocardium of said at least one myocardial segment (see Fig. 12; claim 12; col. 11, line 58 – col. 12, line 10).

Art Unit: 3737

Regarding **claims 11 and 12**, Roundhill et al. teach tracking the apex and control points as the heart is beating and automatically drawing cardiac borders (col. 10, lines 52 – 67; col. 13, lines 12-31).

Regarding **claims 13-21**, Roundhill et al. teach the method steps as discussed above which would necessitate the presence of the corresponding apparatus parts used in the method steps.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 8-10 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Roundhill et al. Roundhill et al. teach the limitations as discussed above but may not explicitly teach presetting values of M-mode and volume. However, it is well known in the art to use anatomical information to preset ultrasound imaging systems and processors. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to preset values of M-mode and volume based on the anatomical scans.

Art Unit: 3737

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/ Supervisory Patent Examiner, Art Unit 3737

/E. C./ Examiner, Art Unit 3737 4/25/2008